



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/602,526

06/24/2003

William R. Noyes

3222.01US02

1769

62274 7590 03/14/2008

DARDI & ASSOCIATES, PLLC

220 S. 6TH ST.

SUITE 2000, U.S. BANK PLAZA

MINNEAPOLIS, MN 55402

EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/602,526 | Applicant(s) NOYES, WILLIAM R. | |
| | Examiner Humera N. Sheikh | Art Unit 1618 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19, 21-24, 29-38 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65 is/are allowed.
- 6) ☒ Claim(s) 17, 19, 21-24 and 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, the Amendment and Applicant's Arguments/Remarks, all filed 12/07/07 is acknowledged.

Applicant has overcome the following amendment by virtue of the amendment and/or persuasive remarks: (1) The 35 U.S.C. 112, 1st paragraph rejection of claims 17-25, 27, 29-38 and 62-64 based on lack of enablement for the species of instant claim 20 has been withdrawn by virtue of the amendment to claim 17, which recites "the first tissue associated with the rectum and the second tissue location associated with the prostate gland" and cancellation of instant claim 20.

Claims 17, 19, 21-24, 29-38 and 65 are pending in this action. Claim 17 has been amended. New claim 65 has been added. Claims 1-16, 18, 20, 25-28 and 39-64 have been cancelled. Claims 17, 19, 21-24 and 29-38 remain rejected. Claim 65 is allowable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1618

Claims 17, 19, 21-24 and 29-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biocompatible filler material made of “collagen”, does not reasonably provide enablement for the selective filler materials of instant claim 21 (i.e., polyethylene glycol). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicant has only established ample support in the specification for the use of “collagen” as a suitable filler material (specification, pp. 5-6). Applicant has not presented sufficient support for any other embodiment regarding the filler materials of instant claim 21. The specification merely states at page 6, lines 7-9, that, “Other materials may be used that include natural or synthetic materials, e.g., proteins...polyethylene glycol-based materials”. This disclosure is not sufficient to support the species of filler materials of instant claim 21 and is found unpatentable.

Response to Arguments

Applicant’s arguments see response on pages 14-18 filed 12/07/07, with respect to the 35 U.S.C. §112, 1st paragraph rejections of claims 17-25, 27, 29-38 and 62-64 have been fully considered and were found to be partially persuasive. The 35 U.S.C. §112, 1st paragraph rejection of claims 17-25, 27, 29-38 and 62-64 based on lack of enablement for the species of instant claim 20 has been withdrawn by virtue of the amendment to claim 17, which recites “the first tissue associated with the rectum and the second tissue location associated with the prostate gland” and cancellation of instant claim 20.

Art Unit: 1618

However, the 35 U.S.C. §112, 1st paragraph rejection of claims 17-25, 27, 29-38 and 62-64 with regards to lack of enablement for additional fillers, asides from collagen, has been maintained. Applicant's arguments were not found to be persuasive. It remains the position of the Examiner that Applicant has not sufficiently demonstrated how the claimed filler materials, other than collagen, work. The different filler materials being claimed (as recited in instant claim 21) are not considered to be equivalent, each with the other. Applicant is only supported for the use of the "collagen" filler.

The rejection of claims 17-25, 27, 29-38 and 62-64 under 35 U.S.C. §112, 1st paragraph has been maintained.

Allowable Subject Matter

Claim 65 is allowed.

Note: Any claim dependent on independent claim 65 would also be allowable.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1618

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

February 29, 2008

Application/Control Number: 10/602,526
Art Unit: 1618

Page 6